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About ECRI Institute

- Independent, not-for-profit applied research institute focused on patient safety, healthcare quality, risk management
- Web site for HRSA grantees. Log in with user id and password at: **www.ecri.org/clinical_RM_program**
- **Have not activated your User ID yet? E-mail us at: clinical_RM_program@ecri.org.**
- 40-year history, 320 person staff
  - AHRQ Evidence-Based Practice Center
  - WHO Collaborating Center
  - Federally designated Patient Safety Organization

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Objectives

- Recall three high risk areas in obstetrical practice
- Recognize recommended practices for risk reduction and patient safety
- Identify ways to avoid communication failures that can lead to adverse obstetric outcomes
- Recognize strategies for improving perinatal safety in the office/clinic setting
- Identify documentation approaches to reduce litigation risk

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Obstetrics: High Risk by the Numbers (and Dollars)

- Obstetricians - 91% have been sued for negligence (ACOG)
- Obstetric cases – highest $$ in damage awards of all specialties
- Multiple plaintiffs (mother and child, father)

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PIAA Data Sharing Project

- >5,400 closed claims involving C-Sections (1985-2009)
- 38% paid with average indemnity $541,883
- Claim frequency is declining but claim severity (average indemnity) is increasing

$$

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PIAA Data Sharing Project

- 49.4% of brain-damaged infant claims resulted in indemnity payment
- Claims for infant-brain damage resulted in the highest average indemnity payment.

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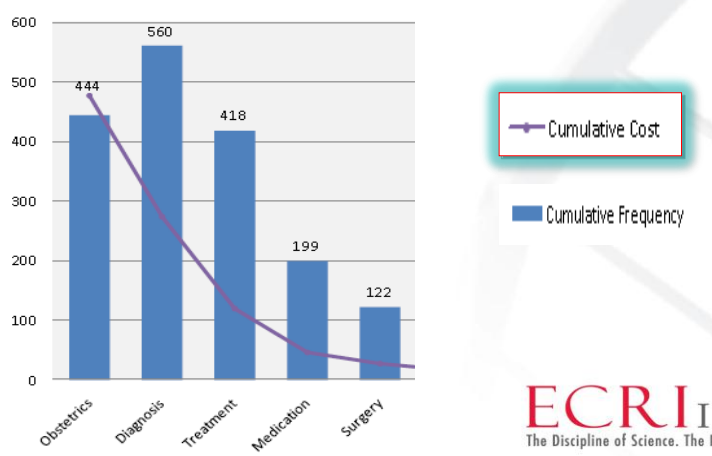
FTCA Health Centers and Providers



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Case Example
Undiagnosed Group B Streptococcus

- Early rupture of membranes
- Antibiotics not given
- Allegations:
  - Neonate showed early signs of infection, traveled to brain
  - Permanent brain damage
- $22.6 million judgment against federal government on behalf of the physicians; $6.5 million settlement reached with the hospital

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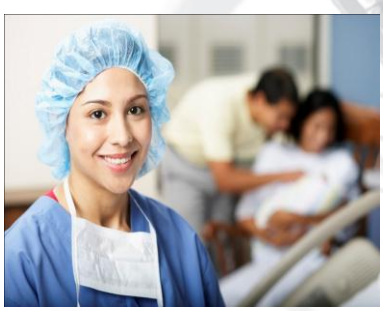
Highest Obstetrical Risk Areas (PIAA)

- Cesarean sections
  - Delays-brain damage
- Forceps deliveries
  - Neonatal injuries
- Shoulder dystocia
  - Identification and management



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PIAA Claims: Associated Issues

- Consent issues, breach of contract or warranty
- Vicarious liability
- Problems with patients history, exam or work up
- Problems with records
- Communication between providers

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Informed Consent—Ob/Gyn Claims

- 10% also involved a consent issue
- 42.6% claims involving a consent issue resulted in an (average) indemnity payment of $153,000
- State law requirements for informed consent
- ACOG Ethics guideline for informed consent (Aug 2009)
- Institutional policy for procedures requiring informed consent (e.g. VBAC, primary elective cesarean section deliveries)

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FTCA Health Centers and Providers Top 5 Obstetric-Related Incidents

- Improper management
- Improperly performed vaginal delivery
- Improper choice of delivery method
- Delay in performance*
- Failure to identify fetal distress

*"Other" category ranked 4th in the KePRO Medical Review and Risk Analysis Summary Annual Report HRSA FY 2009

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Top Secondary Factors: FTCA Health Centers and Providers

- Training and lack of supervision
  - Electronic fetal monitoring
  - Shoulder dystocia; risk factor identification, release maneuvers, event documentation
  - Pre-eclampsia
- Lack of Effective Communication
  - Between primary care provider and OB/GYN specialist
  - Among hospital staff during labor and delivery

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Case – Delayed Response to Fetal Distress

- Obese patient, para 4, pregnancy induced hypertension (controlled with atenolol), and gestational diabetes
- Admitted 3 cm; 50% effaced, -4 station
- Transverse lie, FHR 130/140; Epidural –vertex position, post ARM fluid clear; scalp electrode placed
- 12:30 pm. FHR 70; scalp pH ordered; OB decides C-section
- 12:40 FHR 110-120; scalp stimulation 130-140; cancelled C.
- 12:40 6-7 cm, 75% effaced, -3 station.

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Fetal distress

- 1 pm. FHR dropped; C-ordered; FHR recovers; C-cancelled
- 1-3pm FHR increased; variable decelerations, patient repositioned; OB notified; RN worried, informs head nurse who confers with attending
- 4pm FHR baseline 180
- 4:20 pm FHR drops to 90s/variable decels. Attending tries to get scalp pH while FHR dropping with recurring deep decels.
- Attending unsuccessful; RN pages another OB, but unavailable

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Fetal Distress

- 4:45 pm. Fully dilated; scalp pH severe acidosis
- Patient to OR for vaginal delivery; believes vaginal delivery will be faster than C, but declines vacuum assist.
- Vaginal delivery; tight double nuchal cord; Apgars 1, 3, 5.
- Ped resident transfers to ICU-blood cord pH 6.86
- Metabolic acidosis, hypoxemia, and DIC
- 5th day life support removed; Review: met ACOG criteria for acute intrapartum hypoxic event; autopsy – normal

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Polling Question # 1

If your health center directly provides:

- Pre and post natal care only, press * 1
- Complete obstetrical care through labor and delivery, press *2
- Does not provide direct pre and post natal care, press *3

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Strategies for OB Risk Reduction

- Standardize process and procedures
- Create a culture of safety
  - Empower team members to intervene anytime patient safety is jeopardized
- View Cesarean delivery a process alternative
- Use unambiguous practice guidelines
- Conduct effective peer review

Clark S, et al. AJOG 2008 Aug 105.e1

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Standardized Processes and Procedures

- Perinatal care "bundles"
  - Protocols for administration of oxytocin, misoprostol, and magnesium sulfate
- Operative Vaginal deliveries
  - Criteria for and proper use of vacuum extractor or forceps
- Shoulder dystocia
  - Identification, management (simulation drills), and documentation
- Fetal heart rate abnormalities
  - Guidelines for fetal assessment and provider response

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Perinatal Care Bundles

- Elective induction bundle
  - Gestational age ≥ 39 weeks
  - Monitoring for normal fetal heart rate
  - Pelvic assessment
  - Monitoring and management of tachysystole
- Augmentation Bundle
  - Documented estimated fetal weight
  - Monitoring for normal fetal heart rate
  - Pelvic assessment
  - Monitoring and management of tachysystole

IHI perinatal improvement community: http://www.ihi.org/IHI/Programs/Collaboratives/ImprovingPerinatalCare.htm

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References with samples

- Clark S, et al. Implementation of a conservative checklist-based protocol for oxytocin administration: Maternal and newborn outcomes. *Am J Ob Gyn* 2007;197:480e1-5.
- Clark S, et al. Improved outcomes, fewer cesarean deliveries, and reduced litigation: results of a new paradigm in patient safety. *Am J Ob Gyn* 2008 Aug.
  - Checklist-based protocol for administration of misoprostol in viable term fetuses
  - Checklist-based delivery note supplement for cases of shoulder dystocia
  - Recommended Magnesium Sulfate In-Use Checklist

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Obstetric Patient Safety Strategy

- Risk Assessment by outside experts
- Development of protocols and guidelines
- Patient safety nurse; obstetrical hospitalist (on call attending)
- Anonymous event reporting
- Obstetrical patient safety committee
- Safety culture survey, Team training
- Electronic Fetal Monitoring certification

Pettker C, et al. Impact of a comprehensive patient safety strategy on obstetric events. *Am J Ob Gyn* 2009 May

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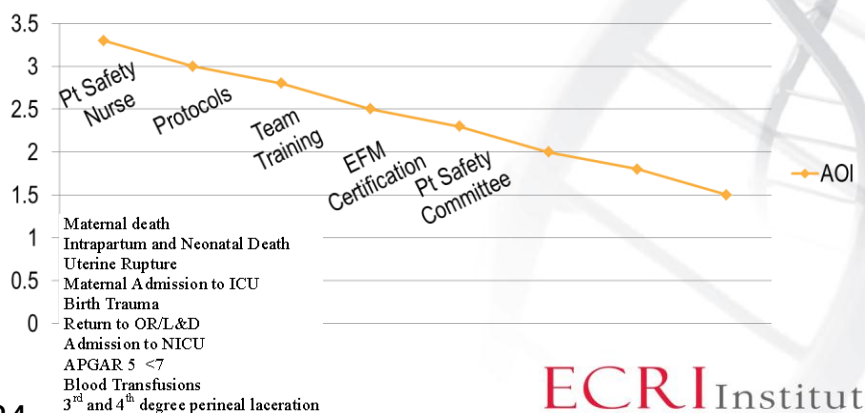
Three Year Trend
Obstetrical Adverse Outcome Index



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Operative Vaginal Deliveries

- Vacuum Delivery Bundle (IHI)
  - Alternative labor strategies considered
  - Prepared patient
    - —Informed consent discussed and documented
  - High probability of success
    - —Estimated fetal weight, fetal position and station known
  - Maximum application time and number of pop-offs predetermined
  - Exit strategy available
    - —Cesarean and resuscitation team available

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Instrumented Delivery Protocol

- No vacuum applied for fetus prior to 36 weeks of gestational age
- No combined usage of forceps and vacuum unless clinically compelling and justified
- No more than 3 pop-offs or 20 minutes maximum total time of application

Mazza F., et al.: Eliminating birth trauma at Ascension Health. *Jt Comm J Qual Patient Saf* 33:15–24, Jan. 2007.
Mazza et al. The road to zero preventable birth injuries. *Jt Comm J Qual Pat Safety* 2008 Apr;34(4):201-5.

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Vacuum Assisted Delivery: Risk Reduction Strategies

- Supplement residency training with mentoring
  - Consider simulation
- Establish protocols, policies
  - Indications/contraindications, total time, max time/pressure, max # pops
  - Conduct teamwork drills to refine communication
- Use a practice "bundle"
- Standardize documentation
- Implement Audits

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Documentation

- Indications for instrumented delivery
- Estimated fetal weight (EFW) relative to the size of the maternal pelvis
- Presentation and station of the fetal head
- Also:
  - Informed Consent
  - Ease of application, duration of traction and use
- CRM Resource: "Preventing Maternal and Neonatal Harm during Vacuum-Assisted Vaginal Delivery"

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Shoulder Dystocia

- 4th most common cause of medical litigation for OB providers
- Reported incidence ranges from 0.2% to 3% of vaginal deliveries
- Mechanical causes
- Internal and/or external maneuvers by delivery provider required

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Table 2. Neonatal Injuries Associated with Shoulder Dystocia Reported to the Pennsylvania Patient Safety Authority, June 2004 through October 2008

NEONATAL INJURIES	NUMBER OF REPORTS	PERCENTAGE OF NEONATAL INJURIES (N = 124)	PERCENTAGE OF ALL SHOULDER DYSTOCIA REPORTS (N = 316)
Skeletal injuries (clavicular fracture, humeral fracture)	51	41%	16%
Decreased limb movement	31	25%	10%
Erb's palsy and brachial plexus injury	15	12%	5%
Crepitus	7	6%	2%
Cephalohematoma/subdural hemorrhage	4	3%	1%
Death	3	2%	1%
Other (audible pop or click, bruising, laceration)	63	51%	20%
Total (may have multiple, overlapping injuries)	174		

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Shoulder Dystocia: Risk Factors

- Maternal risk factors
  - Gestational diabetes, obesity…
- Fetal risk factors
  - Macrosomia
- Clinically applied forces
  - Increased clinically applied traction during fetal manipulation
  - Use of forceps or vacuum extraction

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Shoulder Dystocia Risk Management

- Identification and communication of patients at risk for shoulder dystocia prior to delivery
- Management to minimize potential injury to fetus and mother
  - Documentation and treatment upon discovery
- Interdisciplinary drills for care team that include application of external and internal maneuvers

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Shoulder Dystocia: Clinical Management

- Identify risk factors, document and communicate!
  - Patient history
  - Glucose screening
  - Estimated fetal weight
- Recognize and intervene to relieve shoulder dystocia
  - Apply external/internal maneuvers: McRoberts, Rubin's, Woods, reverse Woods, delivery of posterior arm, "all fours"…
- Simulation Drills

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Documentation

- When/how shoulder dystocia diagnosed
- Progress of labor
- Presence of the "turtle sign"
- Position and rotation of the fetus's head
- Presence of an episiotomy
- Whether anesthesia was required
- Estimated force and duration of traction applied
- Order, duration, and results of maneuvers used
- Duration of shoulder dystocia
- Documentation of adequate pelvimetry before initiating labor induction or augmentation
- Neonatal and obstetric providers impressions of the neonate after delivery
- Information given to the mother
- Personnel involved in delivery

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Improving Communication and Information Flow

- Teamwork and communication
  - In the office/clinic
  - In the hospital or other delivery facility
- Covering providers
- Antenatal/other records to delivery facility
- Obstetric-specific and general office safety resources at the clinical risk management Web site:
  - Self Assessment Questionnaire: Obstetrics
  - Guidance: Communication and patient safety

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Protocols for Decision Support and Documentation

Additional Web site Resources

Standards and Guidelines

- ACOG
  - Guideline: Management of Preterm Labor (http://www.guideline.gov/summary/summary.aspx?doc_id=3993&nbr=003130&string=preterm+AND+birth
- CRICO/RMF Clinical Guidelines for Obstetrical Services
  - (http://www.rmf.harvard.edu/files/documents/obguide_09.pdf)
- And many others…

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Polling Question #2

- If there is one person in the room, press 1
- If there are two people in the room, press 2
- For 3, press 3
- For 4, press 4, etc.
- …
- For 9 or more, press 9

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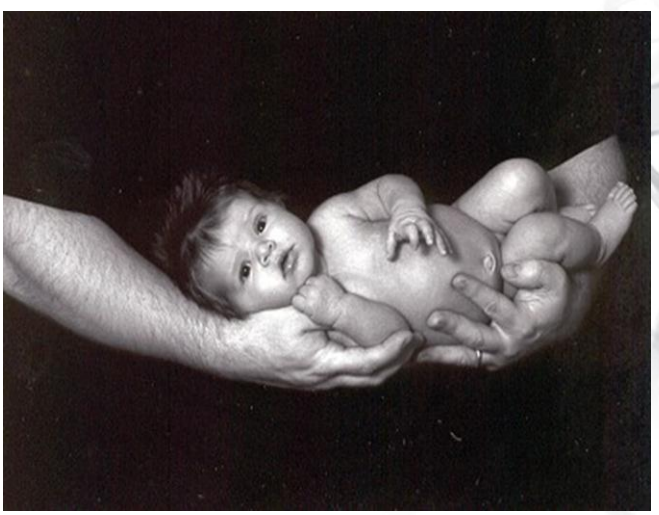

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Thank You!

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